



Attorney's Docket No.: 12020-003002

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : David H. Jones et al. Art Unit : 1632  
Serial No. : 09/898,105 Examiner : D. Nguyen  
Filed : July 3, 2001  
Title : METHOD OF MAKING MICROENCAPSULATED DNA FOR VACCINATION  
AND GENE THERAPY

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

Enclosed are two forms PTO-1449 for the above application. The first form PTO-1449 consists of pages 1-2 and the second consists of pages 1-5.

Under 35 USC §120, this application relies on the earlier filing date of application serial number 09/079,400, filed on May 15, 1998. The references listed on the first form PTO-1449 (pages 1-2) were submitted to and/or cited by the Office in the prior application and, therefore, are not provided in this application.

Copies of the references listed on the second form PTO-1449 (pages 1-5) are enclosed.

This statement is being filed after a first Office Action on the merits, but before receipt of a final Office Action or a Notice of Allowance. A check for \$180 in payment of the late

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1632/1632

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Page : 2 of 2

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submission fee of §1.17(p) is enclosed. Please apply any other charges or credits to Deposit  
Account No. 06-1050, referencing Attorney Docket No. 12020-003002.

Respectfully submitted,

Date: October 1, 2003

  
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Substitute Form PTO-1449

(Modified)

U.S. Department of Commerce  
Patent and Trademark OfficeAttorney's Docket No.  
12020-003002Application No.  
09/898,105

OCT 06 2003

Information Disclosure Statement  
by Applicant  
(Use several sheets if necessary)

(37 CFR 1.98(b))

Applicant  
David H. Jones et al.Filing Date  
July 3, 2001Group Art Unit  
1632

## U.S. Patent Documents

Examiner Initial	Desig. ID	Patent Number	Issue Date	Patentee	Class	Subclass	Filing Date If Appropriate
	AA	4,652,441	03/24/1987	Okada et al.			
	AB	4,711,782	12/08/1987	Okada et al.			
	AC	4,853,226	08/01/1989	Machida et al.			
	AD	4,917,893	04/17/1990	Okada et al.			
	AE	4,933,105	06/12/1990	Fong			
	AF	5,061,492	10/29/1991	Okada et al.			
	AG	5,531,925	07/02/96	Landh et al.			
	AH	5,540,937	07/30/1996	Billot et al.			
	AI	5,622,649	04/22/1997	Hunter et al.			
	AJ	5,639,473	06/17/1997	Grinstaff et al.			
	AK	5,648,095	07/15/1997	Illum et al.			
	AL	5,650,173	07/22/1997	Ramstack et al.			
	AM	5,654,008	08/05/1997	Herbert et al.			
	AN	5,783,567	07/21/1998	Hedley et al.			
	AO	5,814,344	09/29/1998	Tice et al.			
	AP	5,869,103	02/09/1999	Yeh et al.			
	AQ	5,885,590	03/23/1999	Hunter et al.			

## Foreign Patent Documents or Published Foreign Patent Applications

Examiner Initial	Desig. ID	Document Number	Publication Date	Country or Patent Office	Class	Subclass	Translation
							Yes No
	AR	EP 0 145 240	06/19/1985	Europe			
	AS	EP 0 263 490	04/13/1988	Europe			
	AT	EP 0 451 390	10/16/1991	Europe			
	AU	EP 0 779 072	06/18/1997	Europe			
	AV	GB 2234896	02/20/1991	Great Britain			
	AW	GB 2265311A	09/29/1993	Great Britain			
	AX	GB 2310801A	09/10/1997	Great Britain			

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Substitute Form PTO-1449 (Modified)	U.S. Department of Commerce Patent and Trademark Office	Attorney's Docket No. 12020-003002	Application No. 09/898,105
<b>Information Disclosure Statement by Applicant</b> (Use several sheets if necessary) <i>06 2003</i> (37 CFR § 1.98(b))		Applicant David H. Jones et al.	
		Filing Date July 3, 2001	Group Art Unit 1632

Foreign Patent Documents or Published Foreign Patent Applications							
Examiner Initial	Desig. ID	Document Number	Publication Date	Country or Patent Office	Class	Subclass	Translation <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
	AY	WO 95/11009	04/27/1995	WIPO			
	AZ	WO 97/35563	10/02/1997	WIPO			

Other Documents (include Author, Title, Date, and Place of Publication)		
Examiner Initial	Desig. ID	Document
	AAA	Alexakis, T. et al., "Microencapsulation of DNA WithAlginate Microspheres and Crosslinked Chitosan Membranes for In Vivo Application," <u>Appl. Biochem. Biotech.</u> 50:93-106 (1995).
	ABB	Crystal et al., "Transfer of Genes to Humans: Early Lessons and Obstacles to Success", <u>Science</u> 270:404-410 (1995)
	ACC	European Patent Office, English language abstract for Japanese Patent No. 06-009377
	ADD	Etlinger, "Carrier sequence selection-one key to successful vaccines", <u>Imm. Today</u> 13:52-55 (1992)
	AEE	Gunzburg et al., "Virus vector design in gene therapy", <u>Mol. Med. Today</u> 1:410-417 (1995)
	AFF	Ledley, "Nonviral Gene Therapy: The Promise of Genes as Pharmaceutical Products", <u>Hum. Gen. Ther.</u> 6:1128-1114 (1995)
	AGG	Troung, V.L. et al., "Gene Transfer by Gelatin-DNA Coacervate," <u>Proceed. Intern. Symp. Control. Rel. Bioact. Mater.</u> 22:466-467 (1995).
	AHH	Troung, V.L. et al., "Immuno-microsphere as Gene Delivery Vehicle:Targeting of LAMP-1 to Lysosomal Membrane," <u>Proceed. Intern. Symp. Control. Rel. Bioact. Mater.</u> 21:142-143 (1994).
	AII	Whelan, "DNA vaccines for emerging infectious diseases", <u>Emerging Infect. Dis.</u> 2:168-175 (1996)
	AJJ	Yan et al., <u>Journal of controlled Release</u> 32, 231-241 (1994)

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### U.S. Patent Documents

Examiner Initial	Desig. ID	Document Number	Publication Date	Patentee	Class	Subclass	Filing Date If Appropriate
	AA	3,520,970	7/21/1970	Lehmann et al.			
	AB	3,523,906	8/11/1970	Vrancken et al.			
	AC	3,737,337	6/5/1973	Schnoring et al.			
	AD	3,775,537	11/27/1973	Lehmann et al.			
	AE	3,821,422	6/28/1974	Morse et al.			
	AF	3,835,221	9/10/1974	Fulberth et al.			
	AG	3,860,733	1/14/1975	Morse et al.			
	AH	3,943,063	3/9/1976	Morishita et al.			
	AI	3,954,959	5/4/1976	Pedersen			
	AJ	3,972,999	8/3/1976	Tsuk			
	AK	4,016,254	4/5/1977	Seager			
	AL	4,083,949	4/11/1978	Benedikt			
	AM	4,182,778	1/8/1980	Hall et al.			
	AN	4,262,090	4/14/1981	Colby, Jr. et al.			
	AO	4,321,253	3/23/1982	Beatty			
	AP	4,384,975	5/24/1983	Fong			
	AQ	4,462,839	7/31/1984	McGinley et al.			
	AR	4,518,433	5/21/1985	McGinley et al.			
	AS	4,637,905	1/20/1987	Gardner			
	AT	4,897,268	1/30/1990	Tice et al.			
	AU	5,075,109	12/24/1991	Tice et al.			
	AV	5,100,669	3/31/1992	Hyon et al.			
	AW	5,126,147	6/30/1992	Silvestri et al.			
	AX	5,180,765	1/19/1993	Sinclair			
	AY	5,279,708	1/18/1994	Wood et al.			
	AZ	5,354,556	10/11/1994	Sparks et al.			
	AAA	5,366,733	11/22/1994	Brizzolara et al.			

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**U.S. Patent Documents**

Examiner Initial	Desig. ID	Document Number	Publication Date	Patentee	Class	Subclass	Filing Date If Appropriate
	ABB	5,407,609	4/18/1995	Tice et al.			
	ACC	5,413,797	5/9/1995	Khan et al.			
	ADD	5,460,831	10/24/1995	Kossovsky et al.			
	AEE	5,622,657	4/22/1997	Takada et al.			
	AFF	5,643,605	7/1/1997	Cleland et al.			
	AGG	5,648,096	7/15/1997	Gander et al.			
	AHH	5,651,990	7/29/1997	Takada et al.			
	AII	5,652,283	7/29/1997	Boeckh et al.			
	AJJ	5,656,297	8/12/1997	Bernstein et al.			
	AKK	5,662,938	9/2/1997	Vert et al.			
	ALL	5,665,383	9/1997	Grinstaff et al.			
	AMM	5,690,954	11/25/1997	Illum			
	ANN	5,700,486	12/23/1997	Canal et al.			
	AOO	5,723,269	3/03/1998	Akagi et al.			
	APP	5,792,366	8/11/1998	Coville			
	AQQ	5,811,128	9/22/1998	Tice et al.			
	ARR	5,814,344	9/29/1998	Tice et al.			
	ASS	5,853,763	12/29/1998	Tice et al.			
	ATT	5,879,713	3/1999	Roth et al.			
	AUU	5,919,408	7/06/1999	Muller et al.			
	AVV	5,945,126	8/31/1999	Thanoo et al.			
	AWW	6,020,004	2/1/2000	Shah			
	AXX	6,025,337	2/15/2000	Truong et al.			
	AYY	6,048,551	4/11/2000	Hilfinger et al.			
	AZZ	6,096,331	8/1/2000	Desai et al.			
	AAAA	6,113,947	9/5/2000	Cleland et al.			
	ABBB	6,159,502	12/2000	Russell-Jones et al.			

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U.S. Patent Documents							
Examiner Initial	Desig. ID	Document Number	Publication Date	Patentee	Class	Subclass	Filing Date If Appropriate
	ACCC	6,270,795	08/07/2001	Jones et al.			
	ADDD	6,309,569	10/20/2001	Farrar et al.			
	AEEE	20020192651	12/19/2002	Wheeler et al.			

Foreign Patent Documents or Published Foreign Patent Applications							
Examiner Initial	Desig. ID	Document Number	Publication Date	Country or Patent Office	Class	Subclass	Translation
							Yes No
	AFFF	WO 00/03660	1/27/2000	WIPO			
	AGGG	WO 99/58112	11/18/1999	WIPO			
	AHHH	WO 98/51279	11/19/1998	WIPO			
	AIII	WO 97/42940	11/20/1997	WIPO			
	AJJJ	WO 96/36317	11/21/1996	WIPO			
	AKKK	WO 98/31398	07/23/1998	WIPO			
	ALLL	WO 98/31346	7/23/1998	WIPO			
	AMMM	WO 95/21931	8/17/1995	WIPO			
	ANNN	WO 94/18954	9/1/1994	WIPO			
	AOOO	WO 94/04121	03/03/1994	WIPO			
	APPP	WO 97/17063	05/15/1997	WIPO			
	AQQQ	WO 97/03702	02/06/1997	WIPO			
	ARRR	WO 90/13361	11/15/1990	WIPO			
	ASSS	WO 88/08300	11/3/1988	WIPO			
	ATTT	WO 95/03357	2/2/1995	WIPO			
	AUUU	WO 95/03356	2/2/1995	WIPO			
	AVVV	WO 88/01213	2/25/1998	WIPO			
	AWWW	0 122 036	10/17/1984	Europe			
	AXXX	0 761 211	3/12/1997	Europe			
	AYYY	0 257 915	3/2/1988	Europe			
	AZZZ	2 660 556	10/11/1991	France			

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							Yes No
	AAAAA	GB 2,147,501	5/15/1985	United Kingdom			

### Other Documents (include Author, Title, Date, and Place of Publication)

Examiner Initial	Desig. ID	Document
	ABBBB	Allen et al. "Biological Properties of Equine Herpesvirus Type 1 DNA: Transfectivity and Transferring Capacity" <i>Infection and Immunity</i> 22: 34-40 (1978)
	ACCCC	Alonso et al. "Determinants of release rate of tetanus vaccine from polyester microspheres" <i>Pharmaceutical Research (New York)</i> 10(7):945-953 (1993)
	ADDDD	Alpar et al., "Potential of Particulate Carriers for the Mucosal Delivery of DNA Vaccines," <i>Biochemical Society Transactions</i> , 25:337S, (1997)
	AEEEE	Anderson, "Human gene therapy", <i>Nature</i> 392:25-30 (1998)
	AFFFF	Bodmeier et al., "The Preparation and Evaluation of Drug-Containing Poly(dl-lactide) Microspheres Formed by the Solvent Evaporation Method," <i>Pharmaceutical Research</i> , 4:465, 466, 571, (1987)
	AGGGG	Brayden et al. "Microparticle vaccine...immunization", <i>Microbes and Infection</i> 3:867-876 (2001)
	AHHHH	Brown, "Genetchnologie für Einsteiger" (2. Auflage): 29-48
	AIIII	Chang, "Biodegradable Semipermeable Microcapsules Containing Enzymes, Hormones, Vaccines, and Other Biologicals" <i>Journal of Bioengineering</i> , 1:25-32 (1976)
	AJJJJ	Chasin et al. (Editors), "Biodegradeable Polymers as Drug Delivery Systems", University of Washington Libraries, pp.1-41
	AKKKK	Cowsar et al., "Poly(lactide-co-glycolide) Microcapsules for Controlled Release of Steroids", <i>Methods in Enzymology</i> , 112,Pages 101-117 (1985)
	ALLLL	Elsner et al., "Ultrasonic Degradation of DNA" <i>DNA</i> 8: 697-701 (1989)
	AMMMM	Ghaderi et al. "Effect of preparative parameters on the characteristics of poly (D, L-lactide-co-glycolide) microspheres made by the double emulsion method" <i>Int. J. Pharm.</i> 141(1,2):205-216, (1996)
	ANNNN	Jones et al. "Poly(lactide-co-glycolide) microencapsulation of vaccine antigens", <i>J. Biotech</i> 44: 29-36 (1994)
	AOOOO	Li, "Nonviral gene therapy: promises and challenges", <i>Gene Therapy</i> 7:31-34 (2000)
	APPPP	McCluskie et al., "Route and Method of Delivery of DNA Vaccine Influence Immune Responses in Mice and Non-Human Primates", <i>Molecular Medicine</i> 5:287-300
	AQQQQ	Nakano et al., "Sustained Urinary Excretion of Sulfamethizole Following Oral Administration of Enteric Coated Microcapsules in Humans," <i>Int'l. Journal of Pharmaceutics</i> , 4:291-298, (1980)
	ARRRR	Ngo et al., "Computational Complexity, Protein Structure Prediction, and the Levinthal Paradox", <i>Birkhauser Boston</i> 14:492-495 (1994)
	ASSSS	Partidos et al., "Biodegradable Microparticles as a Delivery System for Measles Virus Cytotoxic T Cell Epitopes," <i>MOLECULAR IMMUNOLOGY</i> 33(6):485-491 (1996)
	ATTTT	Spooner et al. "DNA vaccination for cancer treatment", <i>Gene Therapy</i> 2, 173-180 (1995)

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Substitute Form PTO-1449 <i>(Docketed)</i> <i>01 06 2003</i> Information Disclosure Statement by Applicant (Use several sheets if necessary) (37 CFR 54.9(b))	U.S. Department of Commerce Patent and Trademark Office	Attorney's Docket No. 12020-003002	Application No. 09/898,105
		Applicant David H. Jones et al.	
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### Other Documents (include Author, Title, Date, and Place of Publication)

Examiner Initial	Desig. ID	Document
	AUUUU	Tinsley-Brown et al. <i>J. Con. Rel.</i> 66: 229-241 (2000)
	AVVVV	Uchida et al. "Oral Delivery of Poly (lactide-co-glycolide) Microspheres Containing Ovlalbumin as a Vaccine Formulation: Particle Size Study" <i>Biol. Pharm. Bull.</i> 17(9):1272-1276 (1994)
	AWWWW	Urban et al., "The Discovery and Use of HLA-Associated Epitopes as Drugs," <i>Critical Reviews in Immunology</i> , 17:387-397 (1997)
	AXXXX	Verma et al., "Gene therapy-promises, problems and prospects", <i>Nature</i> 389:239-242 (1997)
	AYYYY	Wang et al., "Encapsulation of Plasmid DNA...Gene Delivery", <i>J8: Synthetic Non-Viral Gene Delivery Systems</i> , Keystone, CO, Abst. No. 120, Jan. 19-25, 1998. p. 132
	AZZZZ	Wheeler et al. "Immunogenicity in Guinea Pigs and Tolerance in Grass Pollen-Sensitive Volunteers of Enteric-Coated Grass Pollen Allergens", <i>Int. Archs. Allergy appl. Immun.</i> 83:354-358 (1987)
	AAAAAA	Wheeler, "Stabilized plasmid-lipid particles: construction and characertization", <i>Gene Therapy</i> 6:721- (1999)
	ABBBBB	Wolff et al. "Direct Gene Transfer into Mouse Muscle in Vivo" <i>Science</i> 247:1465-1468 (1990)
	ACCCCC	Woodle, " New Amphipatic Polymer...Liposomes", <i>Bioconjugate Chemistry</i> 5:494-496 (1994)

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